

REMARKS

Claims 21-32 are pending in this application. Claims 22-24 and 29-32 are amended herein for clarity. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. The specification is amended to make the benefit claim clear and proper under 37 C.F.R. § 1.78. Moreover, submitted herewith are a Terminal Disclaimer under 37 C.F.R. § 1.321(c), and an Application Data Sheet under 37 C.F.R. § 1.76(c)(1) which corrects an error in the priority claim. It is believed that these amendments add no new matter. In light of these amendments, the Terminal Disclaimer, the Application Data Sheet, and the following remarks, applicants respectfully request reconsideration of this application, entry of these amendments, and allowance of the claims to issue.

Inventorship

Applicants acknowledge that the Office has granted the Petition to Correct Inventorship under 37 C.F.R. § 1.48(a). The Office states that the application will be forwarded to the Office of Initial Patent Examination for issuance of a corrected filing receipt and correction of Office records to reflect the inventorship as corrected.

Priority

The Office Action alleges that the present application has not correctly claimed priority to the earlier filed PCT application PCT/US99/18674 and therefore has also not met the

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requirements for claiming priority to earlier U.S. Provisional Patent Application No. 60/097,446. Specifically, the Office Action states that applicants have not properly claimed priority of the filing date of PCT/US99/18674 under 35 U.S.C. § 120 but have claimed priority to this PCT under 35 U.S.C. § 119(a) and thus have not met the requirements for claiming priority to the provisional application.

Applicants assert that a proper priority claim was made under 35 U.S.C. § 120 and concede that an improper priority claim under 35 U.S.C. § 119(a) was inadvertently made in the Declaration executed in the parent application. To correct the improper claim under 35 U.S.C. § 119(a), applicants submit herewith an Application Data Sheet under 37 C.F.R. § 1.76(c)(1) to show that PCT/US99/18674 was not a foreign-filed application. Further, to show that the priority claim of the instant application was proper under 35 U.S.C. § 120, the specification is amended herein to make the benefit claim clear and proper under 37 C.F.R. § 1.78. Therefore, for the following reasons, applicants believe that this application is entitled to the benefit of U.S. Provisional Patent Application No. 60/097,446.

On February 2, 2004, the above-identified application was filed with a preliminary amendment. The specification was amended to include the following as the first paragraph:

“This application is a divisional application of and claims benefit of U.S. application no. 09/763,260, filed August 17, 1999, which claims benefit of U.S. Provisional Application No. 60/097,446, filed August 21, 1998, both of which are incorporated herein in their entirety.”

In the Filing Receipt mailed March 15, 2005 and the Office Action mailed September 14, 2005, the Patent Office acknowledges the priority claim as a divisional of U.S. Application No.

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09/763,260 (now U.S. Patent No. 6,685,944) and further acknowledges a priority claim to International Application No. PCT/US99/18674. Applicants point out that inasmuch as Application No. 09/763,260 is a U.S. national phase entry of PCT/US99/18674, the priority claim is not made under 35 U.S.C. §§ 119(a)-(d), but rather under 35 U.S.C. § 120. Further, Applicants maintain that the priority claim in the instant application is to (1) U.S. Application No. 09/763,260 (which is a 371 of PCT/US99/18674), which claims priority to (2) U.S. Provisional Application No. 60/097446, filed August 21, 1998.

Applicants respectfully point out that 35 U.S.C. § 365(c) reads as follows:

35 USC 365(c) recognizes the benefit of the filing date of an earlier application under 35 USC 120. Any international application designating the United States, whether filed with a Receiving Office in this country or abroad, and even though other countries may have also been designated, has the effect of a regular national application in the United States, as of the international filing date. As such, any later filed national application, or international application designating the United States, may claim the benefit of the filing date of the earlier international application designating the United States, if the requirements and conditions of section 120 of title 35 USC are fulfilled.

Applicants maintain that the requirements of 35 U.S.C. § 120 were fulfilled. However, the paragraph in the specification claiming priority has been further amended herein to indicate that Application No. 09/763,260 is a § 371 filing of PCT/US99/18674. M.P.E.P. § 201.11 ¶ 2.11 D states:

The reference required by 37 C.F.R. § 1.78(a)(2) or (a)(5) must be included in an ADS or the specification must contain or be amended to contain such reference in the first sentence following the title. If an applicant includes a benefit claim in the application but not in the manner specified by 37 C.F.R. § 1.78(a) (e.g., if the claim is included in an oath or declaration or the application transmittal letter) within the time period set forth in 37 C.F.R. § 1.78(a), the Office will not require

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a petition under 37 C.F.R. § 1.78(a) and the surcharge under 37 C.F.R. § 1.17(t) to correct the claim if the information concerning the claim was recognized by the Office as shown by its inclusion on the filing receipt. ... Even if the Office has recognized a benefit claim by entering it into the Office's database and including it on applicant's filing receipt, the benefit claim is not a proper benefit claim under 35 U.S.C. § 119(e) or 35 U.S.C. § 120 and 37 C.F.R. § 1.78 unless the reference is included in an ADS or in the first sentence of the specification and all other requirements are met.

Accordingly, the amendment to the specification is made to make the benefit claim clear and proper under 37 CFR 1.78. Thus, applicants respectfully request that the Office enter this amendment and grant the priority claim of the instant application.

No petition or fee is believed to be due as the reference was made in the preliminary amendment filed February 2, 2004, and the claim was recognized by the Office as shown by its inclusion on the filing receipt. However, if a fee is due, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account No. 14-0649.

35 U.S.C. § 101

Claims 22-24 and 29-32 are rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory matter. The Office Action states that the claims do not require that the peptides, proteins, or vectors are isolated and therefore read on human beings comprising such proteins or polypeptides.

Claims 22-24 and 29-32 are amended to conform to the Examiner's suggestion that the term "isolated" be added to each claim. Applicants believe that these amendments overcome the

rejections and respectfully request that these rejections be withdrawn and that amended claims 22-24 and 29-32 be allowed.

35 U.S.C. § 102

Claims 21, 22, and 24 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sarobe *et al.* (*J Clin Invest* 102:1239-1248). Specifically, the Office Action states that the claims read on compositions comprising an isolated peptide of SEQ ID NO:1 and that such peptides and compositions comprising them are disclosed in Sarobe *et al.* as the 8A variant peptide. The Office Action goes on to state that this rejection was made because the present application allegedly does not correctly claim priority to the earlier filed PCT application (PCT/US99/18674) and thus has also not met the requirements for claiming priority to earlier U.S. Provisional Application No. 60/097,446.

Applicants submit herewith an Application Data Sheet under 37 C.F.R. § 1.76(c)(1) to correct an error in the originally filed Declaration in which PCT/US99/18674 was incorrectly listed as a foreign priority document. Moreover, applicants amend the specification herein to make the benefit claim clear and proper under 37 C.F.R. § 1.78 and thus claim priority to U.S. Provisional Application No. 60/097,446, filed on August 21, 1998.

Sarobe *et al.* (*J Clin Invest* 102:1239-1248) was published in September 1998, after the priority date of the instant application, and thus cannot be found to be prior art under 35 U.S.C. § 102. Therefore, applicants respectfully request withdrawal of this rejection and allowance of claims 21, 22, and 24.

35 U.S.C. § 103

A. Claims 25, 26, 28-30, and 32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sarobe as applied to claims 21-24 above and further in view of Chisari *et al.* (U.S. Patent No. 5,709,995 (the ‘995 patent)). The Office Action states that while Sarobe teaches the peptide of SEQ ID NO:1, the reference teaches the synthesis of these peptides rather than recombinant production of the peptides using polynucleotides encoding them. The Office Action goes on to state that the ‘995 patent teaches the production of a similar peptide to SEQ ID NO:1 through recombinant means. The Office Action alleges that it would have been obvious to those of ordinary skill in the art to make polynucleotides encoding SEQ ID NO:1 for the recombinant production of the peptide.

As noted above, applicants herein amend the specification to make clear the priority claim and file herewith an Application Data Sheet under 37 C.F.R. § 1.76(c)(1) to correct an erroneous claim of priority under 35 U.S.C. § 119(a)-(d) that was inadvertently made in the Declaration filed in the parent application, U.S. Serial No. 09/763,260, now U.S. Patent No. 6,685,944. The instant application claims priority to U.S. Provisional Patent Application No. 60/097,446, filed on August 21, 1998. Sarobe *et al.* was published in September 1998 and thus cannot be found to be prior art. Because Sarobe is not prior art, this rejection is rendered moot. Therefore, applicants respectfully request that this rejection be withdrawn and that claims 25, 26, 28, and amended claims 29, 30 and 32 be allowed.

B. Claims 23, 27, and 31 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cabezon *et al.* in view of Choo *et al.* and Sarobe *et al.* The Office Action states that these claims read on compositions comprising full-length core proteins comprising the modified epitope of SEQ ID NO:1, or on polynucleotides or vectors encoding the protein. The Office Action states that Cabezon teaches compositions for the induction of an immune response comprising HCV core protein and that while the reference does not teach the use of a core protein according to SEQ ID NO:2, it does teach a core protein sequence comprising the CTL epitope modified in the Sarobe reference. The Office Action goes on to state that it would thus be obvious to those in the art to use a core protein comprising the modified epitope as disclosed in Sarobe.

The Office Action further states that Choo discloses an alternative HCV core protein sequence, and as Cabezon indicates that any HCV core protein may be used, it would similarly have been obvious to those in the art to use a core protein comprising the sequence disclosed in the Choo reference but modified according to the teachings of Sarobe. The Office Action alleges that the combined teachings of Cabezon, Choo and Sarobe render the claimed invention obvious.

As noted above, applicants herein amend the specification to make clear the priority claim and file herewith an Application Data Sheet under 37 C.F.R. § 1.76(c)(1) to correct an erroneous claim of priority under 35 U.S.C. § 119(a)-(d) that was inadvertently made in the Declaration filed in the parent application, U.S. Serial No. 09/763,260, now U.S. Patent No. 6,685,944. The instant application claims priority to U.S. Provisional Patent Application No. 60/097,446, filed on August 21, 1998. Sarobe *et al.* was published in September 1998 and thus

cannot be found to be prior art. Because Sarobe is not prior art, this rejection is rendered moot. Therefore, applicants respectfully request that this rejection be withdrawn and that claim 27 and amended claims 23 and 31 be allowed.

Double Patenting

Claims 21-32 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 9-11, and 13-15 of U.S. Patent No. 6,685,944. The Office Action goes on to state that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent would anticipate the present claims if applied as prior art and because the present claims provide no non-obvious limitations over the claims of the prior patent.

While applicants do not concede the Examiner's position, a Terminal Disclosure in compliance with 37 C.F.R. § 1.321(c) is submitted herewith. Applicants, therefore, respectfully assert that this terminal disclaimer effectively renders moot any obviousness-type double patenting rejections relating to U.S. Patent No. 6,685,944. By submitting this terminal disclaimer, it is understood that applicants do not admit obviousness-type double patenting exists in this case.

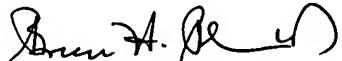
Pursuant to the above amendments, Terminal Disclaimer, Application Data Sheet and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

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A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$130.00 (fee for a terminal disclaimer under 37 C.F.R. § 1.20(d)), a Terminal Disclaimer, and an Application Data Sheet are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

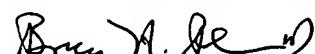


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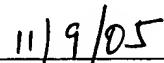
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Date